REMARKS

Applicant respectfully requests reconsideration.

Claims 1-14, 64, 65 and 72-79 were previously pending in this application with claims 6-7 withdrawn from consideration. Claims 1, 64 and 77 have been amended. Support for these claim amendments can be found throughout the specification including, for example, in the Examples and Figures, and on page 20, lines 1-2.

As a result, claims 1-14, 64, 65 and 72-79 are pending for examination with claims 6 and 7 being withdrawn, and 1, 64, 65 and 77 being independent claims. No new matter has been added.

Allowable Subject Matter

Applicant acknowledges the Examiner's conclusion that claim 65 is free of prior art. Claim 65 is not rejected and nor is it dependent upon a rejected claim. Therefore Applicant presumes that claim 65 is allowed.

Rejection Under 35 U.S.C. §103

Claims 1-5, 8-14, 64 and 72-79 are rejected under 35 U.S.C. §103(a) as being unpatentable over Witherell et al. (Current Opinion in Investigational Drugs 2(11);1523-9, 2001) as evidenced by and in view of Hanecak et al. (Journal of Virology 70(8):5203-12, 1996) as evidenced by Kamal et al. (Gastroenterology, 123:1070-83, 2002). Applicant respectfully traverses in part at least for the reasons set forth below:

Independent claim 1 and claims 2-5, 8-14, and 72

Claim 1 has been amended to recite that the CpG immunostimulatory nucleic acid is not administered to a subject in combination with another nucleic acid of a different sequence. Support for this amendment can be found throughout the specification. The specification, including the Examples and the Figures, teaches the use of a single nucleic acid species, and the data show that a single nucleic acid species is effective in stimulating an immune response when contacted to cells such as PBMCs isolated from chronically HCV infected subjects that had previously undergone a

non-CpG therapy and were treatment failures or relapsers. One of ordinary skill reading the specification would have understood that immune stimulation does not require a combination of different nucleic acids and that immune stimulation is effectively induced using just one CpG nucleic acid species. Accordingly, one of ordinary skill would have understood that Applicant had possession of a method of stimulating an immune response by administering a CpG immunostimulatory nucleic acid not in combination with another nucleic acid of a different sequence. Applicant clearly contemplated and was in possession of such a method at the time of filing as reflected in the teachings in the specification. The specification therefore provides the requisite written description for the amended claims. In re Alton, 76 F.3d 1168, 1175 (Fed. Cir. 1996); MPEP 2163.02 citing In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991; Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 974, 63 USPQ2d 1609, 1621 (Fed. Cir. 2002); Ex parte Holt, 19 USPQ2d 1211 (BPAI 1991) ("An invention claimed need not be described *ipsis verbis* in the specification in order to satisfy the disclosure requirements.")

The method of claim 1, as now amended, is not rendered obvious by Witherell et al., Hanecak et al. and Kamal et al. Witherell et al. reports the use of an antisense oligonucleotide ISIS 14803 that contains a methylated CG dinucleotide as an anti-viral agent for HCV infected subjects. Witherell et al. reports that the effectiveness of ISIS 14803 may be limited due to the sequence variability of HCV subtypes and the inability of any single antisense oligonucleotide to target all sequence variations in these HCV subtypes,. To mitigate these limitations, Witherell et al. suggests using ISIS 14803 in combination with additional antisense oligonucleotides of different sequence specificities, including for example ISIS 6095 which according to Hanecak et al. comprises an unmethylated CpG dinucleotide. Witherell et al. reports that combinations of antisense oligonucleotides are necessary to "increase efficacy" and to "reduce resistance [and relapse]." Thus Witherell et al. teaches using ISIS 6095 with ISIS 14803. Witherell et al. does not teach and it does not suggest administering the ISIS 6095 in the absence of another nucleic acid of a different sequence.

Based on the teachings in Witherell et al., one of ordinary skill would not use ISIS 6095 in the treatment of HCV infected subjects without other oligonucleotides. To the contrary, one of

ordinary skill would have used a combination of antisense oligonucleotides, including ISIS 14803, in order to target a number of HCV subtypes. The suggestion by Witherell et al. to combine ISIS 14803 with other antisense oligonucleotides to target several HCV IRES regions teaches away from the administration of a single nucleic acid species as now recited in claim 1. Moreover, based on these teachings one of ordinary skill would not have had a reasonable expectation of success relating to the use of a single nucleic acid species in HCV infected subjects since Witherell et al. specifically teaches that several HCV IRES regions should be targeted by using multiple antisense oligonucleotides.

For at least these reasons, claims 1-5, 8-14, and 72 are not obvious over Witherell et al. in view of Hanecak et al. and Kamal et al.

Independent claims 64, 77 and claims 73-76, 78, 79

Claims 64 and 77 have been amended to recite that the CpG immunostimulatory nucleic acid is not an antisense oligonucleotide. Support for this amendment can be found throughout the specification and in particular at page 20 lines 1-2.

The methods of claim 64 and 77 are not rendered obvious by Witherell et al. in view of Hanecak et al. and Kamal et al. Witherell et al. reports the use of antisense oligonucleotide ISIS 14803, preferably together with other antisense oligonucleotides such as ISIS 6095, in the treatment of certain chronically HCV infected subjects. Witherell et al. does not teach or suggest administering oligonucleotides that are not antisense oligonucleotides. Based on the teachings of Witherell et al., one of ordinary skill would use antisense oligonucleotides in such subjects. Witherell et al. provides no rationale for using oligonucleotides that are not antisense oligonucleotides, as now recited in claims 64 and 77. One of ordinary skill would not have had a reasonable expectation of success for using oligonucleotides that are not antisense oligonucleotides in the treatment of HCV infected subjects in view of Witherell et al.

For at least these reasons, claims 64 and 73-79 are not obvious over Witherell et al. in view of Hanecak et al. and Kamal et al.

Reconsideration and withdrawal of this rejection is respectfully requested.

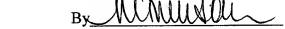
CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23/2825 under Docket No. C1037.70035US01 from which the undersigned is authorized to draw.

Dated: March 1, 2010

Respectfully submitted,

By 

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